

State of California—Health and Human Services Agency

Department of Health Services



Governor

Date: May 21, 2007 IZB-FY0607-10

TO: California Vaccines for Children (VFC) Program Providers

FROM: Howard Backer, MD, MPH, Chief

Immunization Branch

SUBJECT: Unavailability of Merck's MMR-V Vaccine (ProQuad®),

Background

Merck & Co., Inc. has notified all customers that they are unable to supply MMR-V vaccine beginning July 2007 through the end of this year. The California Vaccines for Children (VFC) Program will immediately begin transitioning VFC providers to order separate MMR and varicella vaccine orders, instead of MMR-V.

Earlier in the year, Merck & Co., Inc. notified the Centers for Disease Control and Prevention (CDC) of lower than expected yields of varicella-zoster virus (VZV), which is used in the production of three of their vaccine products: the varicella vaccine (Varivax®), the MMR-V vaccine (ProQuad®), and the zoster vaccine (Zostavax®). Since then, Merck had prioritized production of varicella and zoster vaccines over production of MMR-V vaccine. According to Merck's current projections, ProQuad® will be unavailable beginning in July 2007 and it is not expected to be available for the remainder of 2007.

Merck expects to continue to meet demands for Varivax[®] and M-M-R II[®] to fully implement the recommended immunization schedule. This will allow for continued use of varicella vaccine for all age groups, including the routine two-dose schedule for children ages 12-15 months and 4-6 years, the second dose catch-up vaccination for children or adolescents who received only one dose, and the two-dose vaccination for other children, adolescents, and adults without evidence of immunity.

M-M-R II[®] and Varivax[®] vaccines must not be combined in the same syringe. The vaccines should be administered using separate syringes at different anatomic sites. Correct storage and handling of all vaccines is extremely important and should be reviewed with all office staff. MMR and varicella vaccines are vulnerable to heat and light. Varicella vaccine must be stored at temperatures of 5°F or below; MMR vaccine

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can be stored in the refrigerator or freezer. Adjusting thermostats to lower freezer temperatures in combination refrigerator/freezer units may lower refrigerator temperatures. It is extremely important to be aware of temperatures in all areas of your refrigerator unit and avoid storage of vaccines near vents, in the doors or in the "crisper" areas of the refrigerator units. Inactivated vaccines will be irreversibly damaged by exposure to freezing temperatures.

Further information is available in the CDC's Morbidity and Mortality Weekly Report (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5618a6.htm).

VFC Ordering

Effective immediately and until further notice, California's VFC Program will **not** accept any orders for MMR-V vaccine. Instead, providers should submit orders for MMR and varicella vaccines. We expect that all orders that have been submitted prior to receiving this notice will be filled by Merck. Please remember that orders for MMR-V have been taking 4-5 weeks for delivery.

Any order for MMR-V submitted to the VFC Program after this notification will be automatically processed as single antigen varicella vaccine and MMR vaccine. We will notify you when MMR-V is again available for ordering through the VFC Program.

Varicella vaccine will continue to be shipped directly from Merck, and MMR vaccine will be shipped along with your regular vaccine shipments from the VFC Program's national distributor, McKesson Specialty.

Enclosure: Order Form

cc: DHS Immunization Branch Field Representatives

Local Health Officers

Local Health Department Immunization Coordinators

Local Health Department CHDP Program Directors

Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS

Marian Dalsey, M.D., Chief, Children Medical Services Branch, CDHS

Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care,

CDHS

Susann Steinberg, M.D., Chief, Maternal, Child and Adolescent Health/Office of Family Planning Branch, CDHS

Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB

Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS

Kathy Chance, M.D., Children Medical Services Branch, CDHS

State of California—Hea	lth and	Human Serv	ices Ager	псу						Departme	nt of Health Services	
VACCINES FOR CHILDREN (VFC) PROGRAM VACCINE ORDER FORM FAX TO: (877) 329-9832 NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC, ETC. DELIVERY ADDRESS (Number and Street—No P.O. Boxes) CHECK HERE IF THIS IS A NEW ADDRESS.								DATE		VFC PIN NUMBER (6 digit)	
								CONTACT PERSON				
								CITY		ZIP CODE		
TELEPHONE:	FAX:					EMAIL:		COUNTY:				
DELIVERY: Check all		Tue	From:	to:	(Clo:	sed for lunch from:	to:)	STORAGE CAPACI	TY (Check All T	hat Apply)		
days and times you may receive vaccine. If closed during lunch hour,		Wed				sed for lunch from:	to:)	Small Unit/Under	Refrigerator/Freeze		Commercial/	
		Thur	From:	to:	(Clo	sed for lunch from:	to:)	the Counter Refrigerator	Combination	freezer	Laboratory Grade Unit	
please specify.		Fri	From:	to:	(Clo	sed for lunch from:	to:		# of units	# of units	# of units	
Please complete	all se	ections o	n this	order f	orm	in order for	r VFC to p	rocess your va	accine orde	r.		
	DOS	SES USED	V	ACCINE II	NVEN	TORY (DOSES O	N HAND)		NEW VAC	CINE ORDER		
Vaccines	Number of doses used since last order. Enter "0" if none		Number of doses on hand (Current Inventory)			Lot Number	Expiration Date	Vaccine (Circle Choice)	Doses Requested (Multiples of 10)	Packaging (Check preferred presentation)		
REGULAR ORDER V	FC VAC	CCINES						DAPTACEL®		Single dose v	als – 10 per box	
DТар									ripedia®		Single dose vials – 10 per box	
БТ ар								·		☐ Single dose vials — 10 per box		
DTaP/Hepatitis B/								Infanrix®			ringes – 5 per box	
IPV								Pediarix [®]		☐ Single dose sy	ringes – 5 per box	
Hepatitis A								VAQTA®		Single dose vials – 10 per box		
								Havrix [®]		☐ Single dose syringes – 5 per		
Hepatitis B								ENGERIX B®		☐ Single dose vials — 10 per box ☐ Single dose syringes — 5 per b		
								RECOMBIVAX®	OMBIVAX® Single do		als – 10 per box	
Hepatitis B/Hib								COMVAX®		Single dose vi	als – 10 per box	
Hib								PedvaxHIB®	'edvaxHIB® Single dose		als – 10 per box	
								ActHIB®	ActHIB® Sir		Single dose vials – 5 per box	
HPV								Gardasil®			als – 10 per box	
PV								IPOL®		☐ 10 dose vial☐ Single dose sy	ringes – 10 per box	
Meningococcal Conjugate								Menactra™		Single dose vi	als – 5 per box	
Pneumococcal Conjugate								Prevnar [®]		Single dose s	yringes – 10 per box	
Rotavirus	otavirus							RotaTeq [®]		Single dose to	ibes – 10 per box	
Td								DECAVAC™		☐ Single dose vi ☐ Single dose sy	als – 10 per box ringes – 10 per box	
Tdap								ADACEL			als – 10 per box	
·								BOOSTRIX		☐ Single dose vi☐ Single dose sy	als – 10 per box ringes – 5 per box	
VFC VACCINES STO	RED IN	THE FREE	EZER					VARIVAX®		Single dose vi	als = 10 nor hov	
MMR/Varicella						Curre	VARIVAX® Single dose vials – 10 per box Currently not available. Please order single antigen varicella and MMR vaccines instead.					
MMR								MMR-II®	. varioona and		als – 10 per box	
	IMPO	ORTANT	: IF MY \			D CHOICE AND		IS NOT AVAILABLE ackaging	<u> </u>		VACCINES for CHILMEN CALIFORNIA	

☐ Send the vaccine brand/packaging I circled above when it is available

Place your order with sufficient stock on hand to allow 3-4 weeks for the processing and delivery of your vaccine order.



Instructions for Completing the VFC Vaccine Order Form

In order to ensure that your vaccine order is processed as quickly as possible, the VFC Vaccine Order form <u>must</u> be completely filled out. Fill in all blank sections of the form. Orders submitted in outdated forms may delay the processing of your vaccine order.

Instructions:

1. Enter your clinic's PIN number.

The PIN number is the six-digit Provider Identification Number assigned to your clinic upon enrolling in the VFC Program. (This is not your medical license or CHDP/Medi-Cal provider numbers). Your PIN can be found in the upper, right portion of one of your VFC shipping invoices under the title, "FOR RETURNS, REFER TO". You may contact the VFC Office to obtain your PIN #.

2. Use the same facility name that you used when enrolling in the VFC Program.

The facility name can be found on the packing slips that accompany the vaccine shipments. Do not change this VFC facility name without first notifying the VFC Program in writing, even if the clinic name has changed or is incorrect.

3. Specify the address where the VFC Program should deliver vaccines.

Check the appropriate box on the order form if this is a new address. (Remember to include a letter regarding the change of address with your vaccine order.)

4. Specify all days and times during which you can receive delivery of VFC vaccine.

The VFC Program's wholesale distributor delivers vaccine Tuesday through Friday only. When specifying delivery times, take into account times of the day during which you cannot receive deliveries of VFC vaccine (e.g., lunch).

5. Record usage of all VFC vaccine you have administered since your last order.

This Information is easily obtained from a usage log or any other usage reports (e.g., Registry-generated usage reports).

6. List current inventory of <u>all VFC vaccines</u> when completing the order form.

(Do not report inventories of privately purchased vaccines)

List the amount of VFC vaccine on-hand in your refrigerator and freezer, along with their corresponding lot numbers and expiration dates. You may use a separate sheet of paper to record additional lot numbers if needed. You may also attach a registry-generated inventory report outlining detailed information on lot numbers and expiration dates. However, you must still record the <u>total</u> number of doses on-hand in the order form. This will assist the Customer Service Representatives in approving your vaccine order in a timely manner.

7. Select product choice and indicate the number of vaccine doses requested.

The number of doses requested must be in multiples of 10, since most products are shipped in packages of 10 single dose vials/syringes or 10-dose multi-dose vials.

8. Indicate packaging preference for requested product.

When indicated, check your choice of product presentation or packaging. If you do not specify a vaccine preference or packaging, the VFC Program will send vaccine that is currently on stock.

When Completed:

Fax to: (877) 329-9832 (toll-free)

OR

Mail to: Vaccines for Children Program

State of California Department of Health Services,

Immunization Branch

850 Marina Bay Parkway Building P, Upstairs

Richmond, CA 94804

Always keep a copy for your records!

For Questions Call: (877) 243-8832

OR

Contact your local VFC Representative